



RESEARCH DEVELOPMENTS At Englewood Hospital and Medical Center

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Englewood Hospital and Medical Center’s Clinical Research Center is currently conducting multiple clinical research studies with EHMC physician-investigators from various specialties. These studies expand the treatment options available to our patients and advance the medical knowledge available to all physicians. **This focus on research is integral to EHMC’s mission to be the regional leader in state-of-the-art patient care as the treatments of tomorrow will be determined by the research of today.**

HIGHLIGHT ON CARDIOLOGY RESEARCH

“ISCHEMIA”



Principal Investigator:
Richard Goldweit, MD

This international study is seeking to **establish the standard of care for treating stable ischemic heart disease**. Patients with a diagnosis of mild or moderate ischemia will be randomized to one of two standard approaches: conservative (medicine and lifestyle changes) or invasive (cardiac catheterization with stenting or bypass plus medicine and lifestyle changes). All patients will then be followed via clinic visits and phone calls to provide lifestyle counseling, assess quality of life and monitor for any future cardiac events.

“REVEAL”



Principal Investigator:
Jay Erlebacher, MD

Patients at high risk of developing atrial fibrillation (AF) will receive and be continually monitored by a REVEAL implantable cardiac monitor (ICM). **The REVEAL device is used in this study to detect episodes of AF and to identify incidences that can predict AF onset in high risk patients.** This study will also explore quality of life issues, the AF burden over time, and determine how patients at high risk of having AF utilize the healthcare that is available to them.

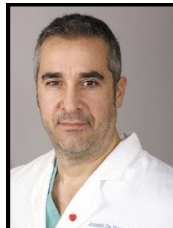
“MULTIPOINT PACING”



Principal Investigator:
David Feigenblum, MD

Cardiac resynchronization therapy (CRT) with biventricular (BiV) pacing has been shown to be an effective treatment for many patients with heart failure. However, not all patients respond to CRT. **This study offers patients access to a new device that allows for MultiPoint Pacing (MPP) consisting of two delayed pulses delivered to two vectors, as compared to the standard BiV pacing in current CRT defibrillator systems.** MPP increases the number of sites and pulses, which may benefit patients who do not respond to conventional BiV pacing.

“ABSORB”



Principal Investigator:
Joseph DeGregorio, MD

This study is evaluating the new ABSORB BVS device, a drug-eluting, bioresorbable vascular scaffold. In contrast to commercially available metal coronary stents that reside permanently in the body, the **ABSORB BVS stent supports the epicardial vessel for an appropriate period and then is resorbed by the body and becomes undetectable over time.** Since the ABSORB BVS will not be a permanent part of the vessel wall, this novel device may lessen local inflammatory reactions and reduce complications for any future bypass surgery that might be needed.



INNOVATION AT EHMC

In addition to offering a growing portfolio of multi-center clinical trials, our Medical Center is also expanding its position as a **leader in original and unique research activities:**

INVESTIGATOR-INITIATED CLINICAL RESEARCH:



“HEMOPURE” Principal Investigator: Aryeh Shander, MD

EHMC was recently granted FDA approval to offer access to HBOC-201 (Hemopure) to patients with life-threatening anemia for whom blood is not an option. HBOC-201 is a Hemoglobin-Based Oxygen Carrier that is not currently approved by the FDA. This investigator-initiated study provides another treatment option for EHMC physicians to use in the care of our many bloodless patients.

“FECAL MICROBIOTA TRANSPLANTATION”

Principal Investigator: Marc Fiorillo, MD

Fecal Microbiota Transplantation (FMT) involves infusing stool from a healthy donor into the bowel of a patient with a *Clostridium Difficile* infection (CDI) in an attempt to restore the natural intestinal flora. Published data indicates that FMT has a success rate of 80%-95% in treating CDI, with no reported adverse occurrences. However, due to a lack of formal prospective studies, the FDA has not approved FMT for the treatment of CDI. This study will allow EHMC patients with CDI to receive FMT, and for the PI to collect additional safety and efficacy data.



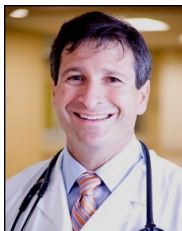
“PaciFIST” Principal Investigator: Kurt Wengerter, MD

This investigator-initiated trial is studying the effect of a small dose of paclitaxel chemotherapy administered to areas of stenosis that may develop in upper-arm arteriovenous dialysis access fistulas. All patients will receive the standard of care treatment for any stenotic lesions and then half will be randomized to also receive the intravascular paclitaxel. The object of the study is to determine whether this additional step can improve outcomes, including the prevention of restenosis.

EXCLUSIVE ACCESS TO INDUSTRY:

“SPECTROSENSE” Principal Investigator: Rosalyn Stahl, MD

EHMC is the only site in the U.S. participating in the testing of the Spectrosense EVA System, which is a device designed to detect the volatile organic compounds (VOCs) found in exhaled breath. The study is focused on trying to find VOCs that are associated with breast cancer. During this early phase of the project, interested patients—both with and without a biopsy-proven diagnosis of breast cancer—are being invited to donate breath samples for this study.



“CAP2” Principal Investigator: Grant Simons, MD

EHMC is the only hospital in New Jersey with access to the Watchman device. Due to his participation in an earlier phase study of this device, Dr. Simons is able to offer EHMC patients with atrial fibrillation expanded access to this novel device. The Watchman device is designed to mechanically prevent the embolization of clots that may form in the left atrial appendage. This device is offered as an alternative to warfarin therapy to prevent ischemic stroke and systemic thromboembolism.



THE PHYSICIAN'S PERSPECTIVE

The EHMC Clinical Research Center can provide the resources needed to carry out a clinical research study, but the initial idea and interest must come from an EHMC Physician-Investigator. All physicians rely on the latest research data to make evidence-based clinical decisions for their patients, but **many EHMC physicians are also the investigators who generate and publish that vital data.** To further increase the number of these EHMC Physician-Investigators, the Clinical Research Center is seeking input from physicians on ways to foster the research environment at the Medical Center.

THE RESEARCH ADVISORY BOARD

The Research Advisory Board is comprised of EHMC physicians who provide insight, from the perspective of the user, on how to improve and grow the Clinical Research Center. This group meets quarterly to discuss current research activities and to strategize on how to expand the program.

A message from the Co-Directors:

“This is our first newsletter highlighting the Clinical Research Center and some important and/or groundbreaking research. The process of ‘bench to the bedside’ can be as short as two years or as long as decades. As part of the mission of medical disciplines, research is dominant in giving direction for cure or improved outcome. Over the years, because of complexities and costs, medical research was limited to academic institutions. That is no longer true. In fact, much of clinical research is a product of non-academic institutions’ participation in research protocols. At EHMC, we are not only participants, but have achieved recognition as leaders in performing original clinical research. With Jamie Ketas’ leadership, we have been able to pull our resources together and grow this venue. Please feel free to inquire, participate or submit work to our Center.”

- Drs. Richard Goldweit and Aryeh Shander

If you are interested in joining the Research Advisory Board, please contact Renee Lockwood at 201.894.3852 or Renee.Lockwood@ehmc.com.

TRAINING AND INFORMATION

Any EHMC physician interested in becoming a Principal Investigator may contact the Clinical Research Center (201.894.3418) or Institutional Review Board (201-894-3852) for information on the training and documentation required.

FUTURE NEWSLETTERS

The Clinical Research Center is striving to increase awareness of our research activities and resources among all EHMC physicians. To that end, upcoming editions of “**RESEARCH DEVELOPMENTS**” will focus on other research programs and opportunities here at the Medical Center. If there is a particular topic or issue you would like to see covered, please let us know.

We also plan to include a section highlighting any publications that result from clinical research activities here at EHMC. Please notify the Clinical Research Center of any research abstracts or articles that have been accepted for publication.



THE EHMC CLINICAL RESEARCH CENTER

RESOURCES AVAILABLE

Our centralized infrastructure coordinates the hospital and research services needed to efficiently run a compliant clinical research study.

All EHMC physicians can utilize the Clinical Research Center to facilitate the standard start-up activities required to open an industry-sponsored clinical trial, including: site qualification surveys and visits, IRB submissions, budget and contract negotiation, regulatory documents, study coordination, and other requirements.



Clinical Research Center Study Coordinators

The Clinical Research Center is also available to assist interested physicians with the additional steps needed to start an investigator-initiated trial, including: FDA submissions, clinicaltrials.gov postings, biostatistical support, publicity/recruiting, and any other study-specific requirements.

CONTINUED GROWTH

EHMC has been conducting clinical research since forming its local Institutional Review Board in 1972. This research legacy is maintained through the steady stream of new physicians joining the Clinical Research Center as Principal Investigators.

The EHMC Clinical Research Center welcomes the following new Principal Investigators:

- Joseph DeGregorio, MD
- Jay Erlebacher, MD
- Marc Fiorillo, MD
- Srikant Kondapaneni, MD
- Kevin Yao, MD

ONGOING PROJECTS

The **Highlight on Cardiology Research** studies and **Innovation at EHMC** projects described in this issue are just a few of the research activities currently running through the Clinical Research Center.

A full listing of all ongoing trials is available on our public website:
http://www.engagewoodhospital.com/mc_clinical-trials_home.asp

If you are interested in learning more about the clinical research opportunities and resources available at Englewood Hospital and Medical Center, please contact the Clinical Research Center at 201.894.3418.



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